

Notice of Allowability	Application No.	Applicant(s)	
	10/584,871	GIGLIOTTI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendment filed 03/09/10.
2. ☒ The allowed claim(s) is/are claims 89-92, now renumbered as claims 1-4 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>121709</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20100604</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
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ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 03/09/10 in response to the non-final Office Action mailed 11/09/09.

Examiner's Amendment

2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by attorney Tate Tischner in a telephonic interview on 04 June 2010.

The instant application has been amended as indicated below.

(a) Paragraph [024] of the specification is replaced with the following:

--[0024] Figure 4 is an alignment of amino acid sequences of inserts used in epitope analysis based on the positions of conserved proline residues. The residues of SEQ ID NOS: 3 (kexin) and 5 (clone A12) are shown.--

(b) Claims 1, 5, 12, 25, 29, 32, 38-43, 45, 46, 48-50, 64, 65, 68, 70, 71 and 74-88 have canceled.

(c) New claims 89-92 have been added as indicated below.

--Claim 89 (New). An isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 5.

Claim 90 (New). A pharmaceutical composition comprising the isolated polypeptide of claim 89 and a pharmaceutically acceptable carrier.

Claim 91 (New). An immunogenic conjugate comprising the isolated polypeptide of claim 89 and a bacterial carrier molecule covalently or non-covalently bound to the polypeptide.

Claim 92 (New). A pharmaceutical composition comprising the immunogenic conjugate of claim 91 and a pharmaceutically acceptable carrier.--

Status of Claims

3) Claims 2-4, 6-11, 13-24, 26-28, 30, 31, 33-37, 44, 47, 61-63, 66-67, 69, 72 and 73 have been canceled via the amendment filed 03/09/2010.

Claims 1, 5, 12, 25, 29, 38, 40-42, 46, 64, 65, 68, 74-76, 79 and 82 have been amended via the amendment filed 03/09/2010.

Claims 1, 5, 12, 25, 29, 32, 38-43, 45, 46, 48-50, 64, 65, 68, 70, 71 and 74-88 have canceled via this Examiner's amendment.

New claims 89-92 have been added via this Examiner's amendment.

Claims 89-92 are pending and are under examination.

Information Disclosure Statement

4) Acknowledgment is made of Applicants' Information Disclosure Statement filed 12/17/09. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Objection(s) Moot

5) The objection to claims 1-5 made in paragraph 15 of the Office Action mailed 11/09/09 is moot in light of Applicants' cancellation of the claims.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 7 of the Office Action mailed 11/09/09 is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Moot

7) The rejection of claims 1-5 and 6-12 made in paragraph 9 of the Office Action mailed 11/09/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

8) The rejection of claims 1-5, 6-8 and 12 made in paragraph 11 of the Office Action mailed 11/09/09 under 35 U.S.C. § 102(b) as being anticipated by WO 98/39424 (ISIS INNOVATION LIMITED, of record), is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 9 and 10 made in paragraph 13 of the Office Action mailed 11/09/09 under 35 U.S.C § 103(a) as being unpatentable over WO 98/39424 (ISIS

INNOVATION LIMITED – Applicants’ IDS) as applied to claim 1, is moot in light of Applicants’ cancellation of the claims.

10) The rejection of claim 11 made in paragraph 14 of the Office Action mailed 11/09/09 under 35 U.S.C § 103(a) as being unpatentable over WO 98/39424 (ISIS INNOVATION LIMITED – Applicants’ IDS) as applied to claim 1 and further in view of Mann *et al.* (US 6,165,469), is moot in light of Applicants’ cancellation of the claim.

Remarks

11) Claims 89-92, now renumbered as claims 1-4 respectively.

The new claims are supported by the cancelled claims 1, 5, 12, 13, 15 and 19.

12) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

13) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner’s voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner’s voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

June, 2010